- (e)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.
- (2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.
- (3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by \$1003.126, or to compromise any penalty and assessment as provided by \$1003.128.

[57 FR 3347, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 36086, July 15, 1994; 59 FR 48567, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 64 FR 39429, July 22, 1999]

§ 1003.107 Determinations regarding exclusion.

- (a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in §1003.106(a).
- (b) With respect to determinations to exclude a person under §§ 1003.102(a) or (b)(1) through (b)(4), the Department considers those circumstances described in §1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.
- (c) In determining whether to exclude a physician under §§ 1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987 and before July 1, 1990, under §1003.105(a)(1)(ii), the Department also considers the access of beneficiaries to physicians' services.
- (d) Except as set forth in paragraph (e), the guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by § 1003.126.
- (e) An exclusion based on a determination under §§ 1003.102(b)(2) or (b)(3) or, with respect to a violation occur-

ring on or after December 22, 1987 and before July 1, 1990, under \$1003.105(a)(1)(ii), may not exceed 5 years.

[59 FR 32126, June 22, 1994]

§ 1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

[59 FR 32126, June 22, 1994]

§ 1003.109 Notice of proposed determination.

- (a) If the Inspector General proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in Medicare, Medicaid and any other Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—
- (1) Reference to the statutory basis for the penalty, assessment and exclusion:
- (2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with §1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);
- (3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;
- (4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);
- (5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

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- (6) Instructions for responding to the notice, including—
- (i) A specific statement of respondent's right to a hearing, and
- (ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and
- (7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.
- (b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion in accordance with §1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.
- (c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

[57 FR 3348, Jan. 29, 1992, as amended at 59 FR 32126, June 22, 1994; 64 FR 39429, July 22, 1999]

§ 1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty, assessment, and exclusion that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and exclusion, with respect to which he or she has not requested a hearing.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3348, Jan. 29, 1992]

§ 1003.114 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability under \$1003.102 has been rendered in

any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

- (b) In a proceeding under this part that—
- (1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and
- (2) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992, as amended at 64 FR 39429, July 22, 1999]

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time prior to a final decision by the Secretary. Thereafter, the General Counsel has such exclusive authority.

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under §1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3348, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of HCFA, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.